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EXAMINER	
HOWARD, ZACHARY C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/051,843	WILLSON ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,8,10,25,28-30,36-38 and 43-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37 and 45* is/are allowed.

6)☒ Claim(s) *1,2,7,8,10,25,28-30,36,38 and 47* is/are rejected.

7)☒ Claim(s) *1,2,7,8,43,44,46,48 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/07 has been entered.

Status of Application, Amendments and/or Claims

The amendment of 11/2/07 has been entered in full. Claims 1, 2, 7, 8 and 47 are amended. Claims 9, 39-42 and 50-52 are canceled.

At pg 7 of the response, Applicants include claim 38 in the list of claims that have been amended. Furthermore, at pg 9 of the response, Applicants state, "claim 38 has been amended to further define the structure and function of the extracellular domain". However, in the 11/2/07 claim listing, claim 38 is listed as being "previously presented" and no amendments to the claim are indicated.

Claims 1, 2, 7, 8, 10, 25, 28-30, 36-38 and 43-49 are under consideration.

Withdrawn Objections and/or Rejections

All objections and/or rejections of claims 9, 39-42 and 50-52 are moot in view of Applicants' cancellation of these claims.

The rejection of claims 48 and 49 under 35 U.S.C. § 112, first paragraph at pg 11-14 of the 4/19/07 Office Action for containing new matter is *withdrawn* in view of Applicants' persuasive arguments at pg 9-10 of the 11/2/07 response. As noted by Applicants, residues 142-1098 of SEQ ID NO: 3 encode residues 28-346 of SEQ ID NO: 4 (the entire extracellular domain of the protein) and residues 142-1338 of SEQ ID NO:

3 encode residues 28-426 of SEQ ID NO: 4 (the entire mature protein). Therefore, residues 142-1098 and 142-1338 are the representative disclosed sequences representing the genus of nucleic acids of claims 43 and 44, and therefore claims 48 and 49 flow naturally from the disclosure in the same manner as claim 43 and 44 (see pg 9 of the 4/19/07 Office Action).

The rejections of claims 48 and 49 under 35 U.S.C. § 112, first paragraph at pg 5-8 of the 4/19/07 Office Action for lack of enablement, and at pg 8-10 for lack of written description, are *withdrawn* on further consideration by the Examiner. It is noted that these dependent claims limit the isolated nucleic acid sequence of claim 1 to one wherein said sequence consists of nucleotides 142-1098 or 142-1338 of SEQ ID NO: 3. As such, the claims are limited to isolated nucleic acids encoding either the entire extracellular domain, or the entire mature protein, of SEQ ID NO: 4.

Claim Objections

Claims 1, 2, 7, 8, 43, 44, 46, 48 and 49 are objected to because of the following informalities:

(1) In the new language added to claim 1, the term "No: 4" (as used in the sequence identifiers) is not capitalized in a consistent manner with the existing claim language ("NO: 4"). For clarity, the term should be fully capitalized (i.e., "NO: 4") throughout the claims. Claims 2, 7 and 8 are objected to for the same reason.

(2) In the new language added to claim 1, the term "α-chain" is not presented in a consistent manner with the existing claim language ("alpha chain"). For clarity, the term should be presented in a consistent manner throughout the claims. Claims 2, 7 and 8 are objected to for the same reason.

(3) Claims 43, 44, 46, 48 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 7, 8, 10, 25, 28-30, 36, 38 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

an isolated nucleic acid molecule comprising a nucleotide sequence encoding an IL-13 receptor α-chain comprising the amino acid sequence set forth in SEQ ID NO: 4 or a nucleotide sequence encoding a derivative of said IL-13 receptor α-chain, wherein the derivative is an extracellular domain of the IL-13 receptor α-chain having at least 95% identity with amino acids 28-346 of SEQ ID NO: 4 and wherein said derivative binds with IL-13; vectors and host cells comprising said nucleic acids; and methods of producing a recombinant polypeptide using said host cells;

does not reasonably provide enablement for

(1) an isolated nucleic acid molecule comprising a nucleotide sequence encoding an IL-13 receptor α-chain comprising the amino acid sequence set forth in SEQ ID NO: 4 or a nucleotide sequence encoding a derivative of said IL-13 receptor α-chain, wherein the derivative is an extracellular domain of the IL-13 receptor α-chain having at least 95% identity with amino acids 28-346 of SEQ ID NO: 4 and wherein said derivative is immunologically interactive with antibodies to said IL-13 receptor α-chain (as recited in claims 1, 2, 7 and 8);

(2) an isolated nucleic acid molecule comprising a nucleotide sequence encoding an IL-13 receptor α-chain comprising an amino acid sequence set forth in SEQ ID NO: 4 (as in claim 2) or having a nucleotide sequence as set forth in SEQ ID NO: 3 (as in claim 7);

(3) an isolated nucleic acid comprising a sequence of nucleotides which encodes an IL-13 receptor α-chain (as recited in claims 7 and 8);

(4) an isolated nucleic acid comprising a sequence of nucleotides which encodes an extracellular domain of an IL-13 receptor alpha-chain (as recited in claim 38);

(5) vectors and host cells comprising the nucleic acids of (1)-(4) above or methods of producing a recombinant polypeptide using said host cells;

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection was set forth previously and maintained at pg 3-9 of the 4/19/07 Office Action.

Applicants' arguments (11/2/07; pg 6-8) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants argue that "in an effort to favorably advance the prosecution, Applicants have amended Claims 1-2, 7-8, 38 and 47" to "further delineate "a haemopoietin receptor" as "as IL-13 receptor α-chain" and further delineate the derivative of the IL-13 receptor α-chain". Applicants argue that these "amendments have adequately addressed the Examiner's enablement rejection directed to the scope of the claims in respect to "derivatives".

Applicants' arguments have been fully considered but are not found persuasive for the following reasons. It is maintained that claims still encompass nucleic acids encoding non-functional derivatives of IL-13 receptor α chain which the specification does not enable the skilled artisan to use.

(1) Applicants have amended independent claims 1, 2, 7 and 8 to include nucleic acids encoding derivatives that have at least 95% identity with amino acids 28-346 of SEQ ID NO: 4 and which bind with IL-13. The specification enables the skilled artisan to make and use such a genus of derivatives that are limited both structurally and functionally. However, the claims also encompass derivatives directed to the functional limitation of "immunologically interactive with antibodies to said IL-13 receptor alpha chain". As set forth previously (4/19/07; pg 6-7), while a skilled artisan could produce non-functional derivatives of SEQ ID NO: 4 that bind to said antibodies, the specification does not enable the skilled artisan use such non-functional derivatives. Antibodies to a protein are only useful if the protein to which they bind has a use. Applicants argued previously that the specification teaches that NR4 or its derivatives can be used to screen for naturally occurring antibodies to NR4 that may occur in autoimmune

diseases (pg 22). This was fully considered in the previous Office Action but was not found to be persuasive for the following reasons. The specification does not provide any guidance regarding which autoimmune diseases, if any, might produce naturally occurring antibodies to NR4. The specification merely invites the skilled artisan to engage in experimentation to screen samples from patients with various autoimmune diseases with NR4 polypeptide to determine if one or more diseases produces antibodies to NR4. Such experimentation is undue in view of the large number of potential autoimmune diseases to be screened and the lack of predictability whether any autoimmune diseases produce antibodies to NR4. Furthermore, the specification does not teach the structure of any “non-functional” NR4 derivatives that are found in patients with autoimmune diseases. Certain positions in the sequence may be critical determinants of a proteins’ antigenicity, and derivatives of NR4 may lack these critical positions. Therefore, even if an autoimmune disease produced antibodies to NR4, it is not predictable which derivatives of NR4 could be used to screen for antibodies. Applicants' 11/2/07 response does not address these issues of record regarding the use of non-functional derivatives that bind antibodies to the IL-13 alpha chain.

(2) Claim 2 encompasses nucleotide sequences "comprising an amino acid sequence as set forth in SEQ ID No: 4", as compared with claim 1, which recites "comprising the amino acid sequence as set forth in SEQ ID No: 4". These two phrases result in claims of very different scope, because the first encompasses nucleic acids that comprise nucleic acids encoding the full-length sequence of SEQ ID NO: 4 or any portion (fragment) of SEQ ID NO: 4. The second phrasing claims only nucleic acids that comprise nucleic acid encoding the full length of SEQ ID NO: 4. Thus, despite Applicants' amendments that limit the derivatives to ones comprising a sequence having at least 95% identity to residues 28-346 of SEQ ID NO: 4, claims 2, 7, 8 (and dependent claims) still encompass nucleic acids encoding a vast genus of derivatives of SEQ ID NO: 4 that are not limited to 95% identity to residues 28-346 of SEQ ID NO: 4. The rejection of these derivatives is maintained for the reasons of record. It is noted that this portion of the rejection could be rendered moot if claim 2 is amended (in lines 2-3) to recite "comprising the amino acid sequence set forth in SEQ ID NO: 4". Similarly, claim

7 encompasses nucleotide sequences "having a nucleotide sequence as set forth in SEQ ID NO: 3", which includes derivatives encoded by variants comprising fragments of SEQ ID NO: 3. The rejection of these derivatives is maintained for the reasons of record. It is noted that this portion of the rejection could be rendered moot if claim 7 is amended (in line 3) to recite "having the nucleotide sequence as set forth in SEQ ID NO: 3".

(3) Claims 7 and 8, while amended, still encompasses "a sequence of nucleotides which encodes an IL-13 receptor α-chain or…" This portion of each claim is not limited by the new claim amendments, which are directed solely to "the derivative". Thus the first portion of the claim still encompasses an essentially unlimited (both structurally and functionally) genus of variants encompassed by the phrase "an IL-13 receptor α-chain". The rejection of these derivatives is maintained for the reasons of record.

(4) As noted above, claim 38 is listed in the 11/2/07 claim listing as being "previously presented" and no amendments to the claim are indicated. Therefore, the rejection of claim 38 is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

Claims 1, 2, 7, 8, 10, 25, 28-30, 36, 38 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection was set forth previously and maintained at pg 9-11 of the 4/19/07 Office Action.

Applicants' arguments (11/2/07; pg 8) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response, Applicants argue that the amended claims are adequately described because claimed derivatives are now characterized structurally by comprising amino acids 28-346 of SEQ ID NO: 4 or at least 95% identity with said amino acids, and

functionally by binding with IL-13 or being immunologically interactive with antibodies to the IL-13 receptor α-chain.

Applicants' arguments have been fully considered but are not found persuasive. The claims still encompass a vast genus of variants of an "IL-13 receptor α-chain" as described above in the section titled "Claim Rejections - 35 USC § 112, 1st paragraph, enablement". The specification does not provide a written description of each full genus of functional variants for the reasons set forth previously.

Claim Rejections - 35 USC § 112, 1st paragraph, new matter

Claim 38 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter. This rejection was set forth previously and maintained at pg 12-14 of the 4/19/07 Office Action.

In the response, Applicants argue that "claim 38 has been amended to further define the structure and function of the extracellular domain."

Applicants arguments have been fully considered but are not found persuasive. As noted above, in the 11/2/07 claim listing claim 38 is listed as being "Previously presented" and no amendments to the claim are indicated. Therefore, the rejection of claim 38 is maintained for the reasons of record. Specifically, claim 38 encompasses any extracellular domain from any IL-13 receptor alpha chain. In addition to nucleic acids encoding full-length receptors, this genus encompasses nucleic acids comprising fragments consisting solely of extracellular domains. The specification teaches a single example of this, a nucleic acid consisting of the extracellular domain of SEQ ID NO: 2. Due to the strong homology between SEQ ID NO: 2 and 4, and the general teachings of the specification about soluble IL-13Rα, a nucleic acid consisting of the extracellular domain (Thr27 to Thr344) of SEQ ID NO: 4 would also flow naturally from the specification. However, there is no conception in the specification of a genus of isolated nucleic acid molecules comprising any extracellular domain from any IL-13 receptor alpha chain. Nor does this genus flow naturally from the disclosure of the specification. Therefore, the specification as originally filed lacks support for claim 38.

Conclusion

Claims 37 and 45 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646